

REMARKS

Applicants express gratitude to the Examiner for indicating present claims 1-32 as allowable.

Applicants respectfully request reconsideration and withdrawal of the outstanding Office Action rejections in view of the foregoing amendments and following remarks. Claims 39, 40, 42-44, and 47 have been amended to put the application in better condition for allowance. Applicants submit that the claim language has only been amended to clarify the claim language to better comply with the written description requirement, do not enter any new matter, and should therefore be entered. No new matter has been added.

Claim Rejections- 35 USC § 112

Claims 39-46 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that according to claim 39, one can utilize any of the listed polypeptide domains, regardless of source, to treat any disease state. Applicants submit that the disclosure on page 9, lines 1-23 of the specification provides clear written support for administering the bacterial cell containing a nucleic acid that encodes a polypeptide capable of eliciting an immune response to the particular disease to be treated, e.g. tuberculosis in Example 1. Thus, it appears that the rejected claims do not adequately reflect this description to the Examiner's satisfaction because the Examiner asserts that the capability of the domain to elicit "an" immune response is not restricted to an immune response to the disease state, but can be any immune response.

Applicants submit that the claims have been amended to clarify and explicitly restrict the claimed method to these specific embodiments. Thus, claim 39 has been amended to additionally recite:

A method of treating a mammal having a disease state, comprising administering to the mammal a bacterial cell according to claim 1 which comprises a recombinant nucleic acid molecule encoding a fusion polypeptide that elicits an immune response to said disease state, in a pharmaceutically effective amount, wherein said polypeptide domain capable of eliciting an immune response to said disease state is selected from the group consisting of autoantigens, tumor antigens, virus antigens, parasite antigens, bacterial antigens and immunogenic fragments thereof that elicit an immune response to said disease.

The amendment is supported by claim 1 and page 9, lines 1-4 of the specification.

With regard to claim 40, Applicants submit that the claim has been amended to additionally recite that the polypeptide domain is capable of eliciting an immune response to tuberculosis is selected from the group consisting of Mycobacterium antigens Ag85B (M. tuberculosis), Ag85B (M. bovis), Ag85A (M. tuberculosis), and ESAT-6 (M. tuberculosis) or an immunogenic fragment thereof that elicits an immune response to tuberculosis, which is supported by claim 8.

With regard to claim 42, the Examiner appears to contend that the recitation "a HIV antigen" is not restricted to HIV antigens capable of eliciting an immune response to HIV infection. Applicants submit that claim 42 depends from claim 39 which, as amended, requires that the domain elicit an immune response to said disease. Further, claim 42 has been amended to specify that the immune response is to said HIV infection.

Similarly, claims 43 and 44 have been clarified by the addition of the recitations, “elicits an immune response to said tumor” and “elicits an immune response to said superficial bladder cancer.”

Claims 45 and 46 depend from claim 39 and should be allowable for at least the same reasons as above.

Claim 47 was rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Although Applicants submit that claim 47 should now be allowable based on the amendment of claim 43 upon which claim 47 depends, to be as explicit as possible, Applicants have amended claim 47 to recite that the tumor antigens **elicit an immune response to said tumor**.

Thus, based on the above, Applicants submit that claims 39-47, as amended, comply with the written description requirement. Because these claims merely clarify and restrict the claims to the described method, Applicants respectfully request that the amendments be entered.

Conclusions

In view of the foregoing amendment and remarks presented herein, all of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Early and favorable action is awaited.

Applicant believes that a full and complete reply has been made to the outstanding Office Action and a Notice of Allowance is respectfully solicited.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any fees and to credit any overpayments that may be required with respect to this paper to Counsel's Deposit Account No.02-2135.

Respectfully submitted,

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